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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,346	07/29/2004	Yaeta Endo	3190-059	7726

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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/500,346		ENDO ET AL.	
	Examiner		Art Unit	
	Celine X. Qian Ph.D.		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 15, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-14, 16, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1104,0604</u> . | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1636

DETAILED ACTION

Claims 1-20 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 1/15/07 is acknowledged. The traversal is on the ground(s) that unity of the invention was found with respect to many of the claims in the PCT application. Applicants further assert that the claims should be examined together since there would not have been a serious burden because the search would be overlap. Applicants assert that the claims should be rejoined upon the allowability of Group II.

The above arguments have been fully considered but deemed not persuasive. As set forth in MPEP 1893.03(d) [R-3] 37 CFR 1.499, it states "If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner." Although the PCT search authority found unity of the invention among some claims, the national stages may still require the restriction according to U.S. practice. MPEP further set forth guidelines for lack of unity practice, "The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so

Art Unit: 1636

linked as to form a single general inventive concept. A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.” In the instant case, the special technical feature of each groups are different from each other for reasons set forth in the previous office action. As such, the requirement is still deemed proper and is therefore made FINAL.

During a telephone conversation with Mr. Kilyk on 2/13/07 a provisional election was made with traverse to prosecute the invention of Group II, claims 10-14, 16, 19, 20 and claims direct to SEQ ID NO:11. Affirmation of this election must be made by applicant in replying to this Office action. Accordingly, claims 1-9, 15, 17, 18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 10-14, 16, 19 and 20 are currently under examination.

Claim Objections

Claims 10, 14, 16, 19 and 20 are objected to for depending on non-elected claims. Applicants are advised to re-write the claims in independent form which includes all limitations of the parent claims.

Claim 11 is objected to for containing non-elected sequences.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1636

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10, 14, 16, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dix et al (Biochemistry, 1992, Vol.31, pages 2818-2822).

Claims 10, 19 and 20 are drawn to a polynucleotide obtained by the method of claims 1, 2 or 3. They are product by process claims which read on the product, a polynucleotide having the activity of regulating translation efficiency, in which the process that made the product does not impart a structural difference to the product. Claims 14 and 16 are drawn to a template and a vector that comprises the polynucleotide having translation regulatory activity.

Dix et al. disclose an IRE isolated from 5' untranslated region of ferritin mRNA in wild type and mutant form which regulates the translation (see page 2819, 2nd col., 3rd paragraph, and Figure 1). Dix et al. also disclose a template and a vector that comprises said IRE (see page 2819, 1st col., 2nd paragraph). Therefore, Dix et al. disclose the instantly claimed invention.

Claims 10, 12, 14, 16, 19 and 20 are rejected under 35 U.S.C. 102(e) as being by Papkoff (US 6,475, 784).

Claims 10, 19 and 20 are drawn to a polynucleotide obtained by the method of claims 1, 2 or 3. They are product by process claims which read on the product, a polynucleotide having the activity of regulating translation efficiency, in which the process that made the product does not impart a structural difference to the product. Claims 14 and 16 are drawn to a template and a vector that comprises the polynucleotide having translation regulatory activity. Claim 12 recites

Art Unit: 1636

a polynucleotide having an activity of regulating translation efficiency, comprising an artificial random sequence of a length of 3 to 200 mer.

Papkoff disclose a vector that comprises a Kozak consensus sequence, GCCGCC, which regulates translation efficiency (see col. 10, lines 41-44). This sequence is an artificial random sequence and has translation regulatory activity. Therefore, Papkoff disclose the instantly claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . . [emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such

Art Unit: 1636

descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. Claim 11 is drawn to a polynucleotide having translation enhancement activity comprising SEQ ID NO:11. The specification discloses SEQ ID NO:11 is a 57 nt random nucleotide which is isolated from the ribosomal fraction after 3 cycles of reaction. The specification also discloses that some of the random nucleotide of 22 nt and 57 nt enhances translation as demonstrated in Figure 2-5. However, it unclear whether the nucleotide sequence is one of them. A review the entire specification does not reveal whether the sequence of SEQ ID NO:11 has translation enhancement activity. As such, this sequence lacks sufficient description for its claimed function.

Claim 12 and 13 are drawn to a nucleotide having random artificial sequence of 3-200 nt and have translational regulatory activity, wherein the activity is equal or greater than the activity of a 5'non-translated leader sequence of an RNA virus. The claimed genus of nucleotide comprises a large number of nucleotides ranging from 3-200 nt of various sequences. However, the instant specification only discloses several (no more than 8, since Figure 4 is not legible in determine which of the nucleotide have greater activity than tomato mosaic virus leader sequence) nucleotides of either 22nt or 57nt have equal or greater activity than the tomato mosaic virus leader sequence. The specification does not teach what common structure these

Art Unit: 1636

nucleotides must share for having such activity except they are screened from a population of randomly synthesized nucleotides. In view of the large genus as claimed, the specification failed to disclose a representative number of species by their complete structure, nor by other identifying characteristics. Therefore, the written description requirement is not met.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER

